K062869

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FEB 26 2007

510(k) Summary

Company Ethicon Endo-Surgery, LLC
Angora Industrial Park, Building G
Caguas, Puerto Rico 00725

Contact Dennis Hahn
Director, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
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Cincinnati, OH 45242
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Date Prepared February 21, 2006

Device Name Trade Name: CONTOUR™ Curved Cutter Stapler and Reloads
Common or Usual Name: Cutter/Stapler and Reloads
Classification Name: Staple, Implantable

Predicate Devices K040038 - Curved Cutter Stapler
K061156 - ENDOPATH® Linear Cutters and Staplers

Device Description: The CONTOUR™ Curved Cutter Stapler is a multifire, single patient use device with a curved head that cuts and staples. The device delivers four staggered rows of titanium staples, with a knife between the second and third row of staples, and creates a 40 mm curved transection. The device is designed with a feature which prevents closing if a used reload or no reload is in the instrument. Another feature is provided to prevent firing unless the closure trigger is latched in the closed position. A retaining pin holds tissue in place and can be positioned either manually or by squeezing the closure trigger. The instrument may be reloaded five times, for a maximum of six firings per instrument during a single procedure. Each reload cartridge module includes a knife blade with two staggered rows of staples on each side, an anvil, a cutting washer, a retaining pin, and a staple retainer. Reload cartridges are available in two sizes: a blue cartridge for compressed tissue with a thickness of 1.5mm, and a green cartridge for compressed tissue with a thickness of 2.0mm.

Indications for Use: The CONTOUR™ Curved Cutter Stapler and Reloads is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or minimally invasive general (gastrointestinal and skeletal muscle), gynecologic, urologic, and thoracic surgical procedures.

Technological Characteristics: The CONTOUR™ Curved Cutter Stapler is identical to the Curved Cutter Stapler predicate device with respect to technological characteristics. The CONTOUR™ Curved Cutter Stapler has the same intended use as the ENDOPATH® Linear Cutters and Staplers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ethicon Endo-Surgery, LLC
% Mr. Dennis Hahn, RAC
Director, Regulatory Affairs
4545 Creek Road
Cincinnati, Ohio 45242

FEB 26 2007

Re: K062869
Trade/Device Name: CONTOUR™ Curved Cutter Stapler and Reloads
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW, GAG
Dated: January 29, 2007
Received: January 31, 2007

Dear Mr. Hahn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062869

Indications for Use

510(k) Number (if known): K062869

Device Name: CONTOUR™ Curved Cutter Stapler and Reloads

Indications for Use:

The CONTOUR™ Curved Cutter Stapler and Reloads is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or minimally invasive general (gastrointestinal and skeletal muscle), gynecologic, urologic, and thoracic surgical procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062869